Research addresses the threat of Zika virus to the US blood supply

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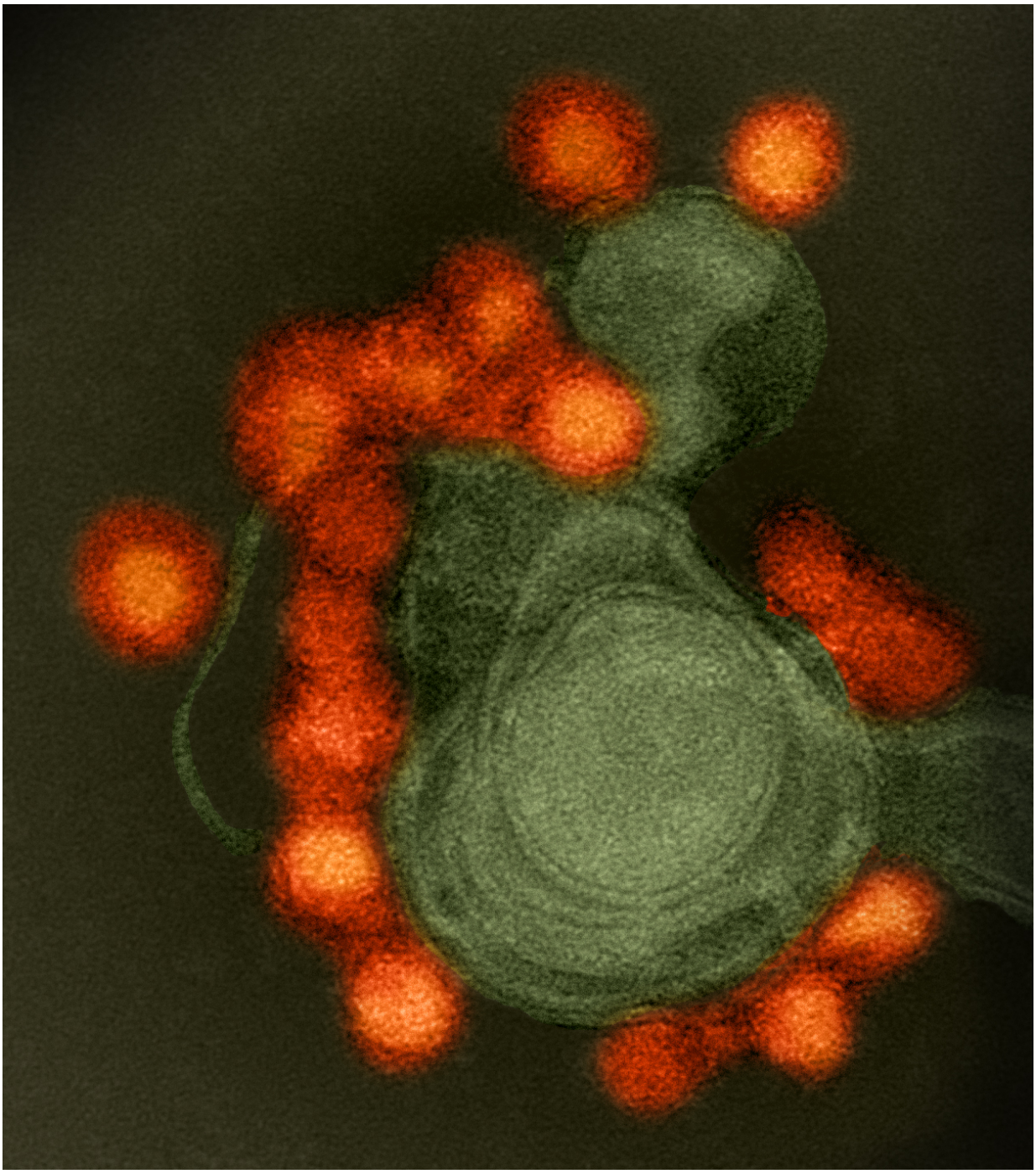

Transmission electron microscope image of negative-stained, Fortaleza-strain Zika virus (red), isolated from a microcephaly case in Brazil. The virus is associated with cellular membranes in the center. Credit: NIAID

Investigators have shown that certain screening methods that detect the genetic material of Zika virus can be used to ensure that donated blood supplies remain free of the virus.

The methods, called Zika virus nucleic acid amplification technology assays, demonstrated similar excellent sensitivities to assays currently used for screening for transfusion-transmitted viruses. The methods were substantially more sensitive than most other laboratory-developed and diagnostic Zika virus assays.

"The results of this study, that evaluated 17 Zika virus assays in 11 laboratories and documented excellent sensitivity of the two donor screening assays manufactured by Roche and Grifols, were critical to support the decision by the U.S. Food and Drug Administration [FDA] and blood industry to implement investigational screening of donors in Puerto Rico in April 2016 and the entire U.S. by the end of 2016", said Dr. Michael Busch, senior author of the study. "Given the sensitivity of these assays, the FDA approved clinical trials using individual donation screening and rescinded earlier policies precluding transfusion of blood collected in Puerto Rico and deferral from donation by donors who had travelled to Zika risk countries throughout the U.S. This screening has detected over 350 infected blood donations in Puerto Rico and dozens of infected donations in the continental U.S."

The research is published in *Transfusion* and is part of a special "Themed Issue" that focuses on Zika virus.

Two other articles in the special issue report on the first blood donations in the continental United States found to be positive for Zika virus infection. The first notes that of 358,786 donations screened, 23 were initially reactive on Roche cobas Zika, a test approved under a FDA's investigational new drug application. Fourteen of these donors, all from Florida, represented probable Zika virus infection based on reactivity in

additional nucleic acid tests or anti-Zika immunoassays. Risk factors included recent travel to Zika virus-active areas and potential sexual exposure. In the second article, the Grifols Procleix Zika assay was used to test 466,834 donations, and five confirmed infected donors with travel exposures were detected outside areas considered as having active transmission. These donors most likely represent travel-acquired "tail-end infections" who had prolonged red blood cell-associated Zika virus RNA. The estimated specificities of both the Roche cobas Zika test and Grifols Procleix Zika tests were >99.99%.

As noted in an accompanying editorial, 10 articles in the special issue are categorized into five themes: nucleic acid testing to detect Zika virus, nucleic acid testing to screen the blood supply in the United States, pathogen reduction of Zika virus in blood components, inactivation of Zika virus during the manufacture of plasma derivatives, and defining those at high risk for complications from transfusion-transmitted Zika virus.

"As the papers in this issue illustrate, building on experience with prior emerging infectious diseases, much has been learned in the relatively brief period of a year both about the nature of the virus and its epidemiology. This knowledge is invaluable as we refine the response to this epidemic," wrote the authors of the editorial. "However, in addition to uncertainty regarding whether Zika virus will spread further or become endemic in some areas, there is also much that remains unknown about the complications of infection itself."

More information: Peter W. Marks et al, Decision making in the face of uncertainty: the challenge of emerging infectious diseases, *Transfusion* (2017). DOI: 10.1111/trf.14037

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